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## NOTICE OF ALLOWANCE AND FEE(S) DUE

33072 7590 08/29/2008

KAGAN BINDER, PLLC  
SUITE 200, MAPLE ISLAND BUILDING  
221 MAIN STREET NORTH  
STILLWATER, MN 55082

EXAMINER

STROUD, JONATHAN R

ART UNIT

PAPER NUMBER

3774

DATE MAILED: 08/29/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,057

02/25/2004

Gregory H. Lambrecht

VIA-3 CON  
(MTI0900/US/2)

9535

TITLE OF INVENTION: CARDIAC VALVE PROCEDURE METHODS AND DEVICES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	12/01/2008

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
Commissioner for Patents  
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

33072 7590 08/29/2008

KAGAN BINDER, PLLC  
SUITE 200, MAPLE ISLAND BUILDING  
221 MAIN STREET NORTH  
STILLWATER, MN 55082

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,057 02/25/2004 Gregory H. Lambrecht VIA-3 CON 9535

TITLE OF INVENTION: CARDIAC VALVE PROCEDURE METHODS AND DEVICES

(MTI0900/US/2)

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$720 \$300 \$0 \$1020 12/01/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
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STROUD, JONATHAN R 3774 623-015000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_

3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee  
☐ Publication Fee (No small entity discount permitted)  
☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.  
☐ Payment by credit card. Form PTO-2038 is attached.  
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,057	02/25/2004	Gregory H. Lambrecht	VIA-3 CON (MTI0900/US/2)	9535
33072	7590	08/29/2008	EXAMINER	
KAGAN BINDER, PLLC SUITE 200, MAPLE ISLAND BUILDING 221 MAIN STREET NORTH STILLWATER, MN 55082			STROUD, JONATHAN R	
			ART UNIT	PAPER NUMBER
			3774	
DATE MAILED: 08/29/2008				

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 752 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 752 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/787,057	LAMBRECHT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jonathan Stroud	3774	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 5/22/08.
2. ☒ The allowed claim(s) is/are 2,48 and 49.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date <u>2/25/04, 11/12/04, 12/14/06, 6/22/07 and 3/4/08</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date ____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other ____.</li> </ol> |
|---|--|

/Thomas J Sweet/  
Primary Examiner, Art Unit 3774



## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of group III in the reply filed on 05/22/2008 is acknowledged. Applicant's arguments concerning claim 2 have been considered and are persuasive; therefore claim 2 has been included in group III and the claims to be examined. Claims 1, 3-26, 32-45 have been withdrawn.

## **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Binder on 8/7/2008. Applicant agrees to cancel all other claims other than claims 2, 48, 49 and to amend the claims as follows:

1. canceled
2. (original) A method for performing an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:
  - a) positioning a first valve as a ~~at least one~~ temporary valve in a flow path of a blood vessel without affixing the temporary valve to the blood vessel and positioned downstream from said cardiac valve, said temporary valve being operative to effect greater antegrade flow than retrograde flow through said vessel;
  - b) resecting at least a portion of the cardiac valve; and

Art Unit: 3774

c) affixing a second valve as a ~~at least one~~ prosthetic valve at or downstream from said resected cardiac valve; and

d) removing the temporary valve from the flow path.

3. canceled

4. canceled

5. canceled

6. canceled

7. canceled

8. canceled

9. canceled

10. canceled

11. canceled

12. canceled

13. canceled

14. canceled

15. canceled.

16. canceled

17. canceled

18. canceled

19. canceled

20. canceled

21. canceled

22. canceled

23. canceled

24. canceled

25. canceled

26. canceled

27. canceled

28. canceled

29. canceled

30. canceled



31. canceled

32. canceled

33. canceled

34. canceled

35. canceled

36. canceled

37. canceled

38. canceled

39. canceled

40. canceled

41. canceled

42. canceled

43. canceled

44. canceled

45. canceled

Art Unit: 3774

46. canceled

47. canceled

48. (currently amended) A method for enabling performance of an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:

a) placing at least one temporary valve in a flow path of blood vessel without affixing the temporary valve to the blood vessel, said temporary valve being operative to effect greater antegrade flow than retrograde flow through said vessel; ~~and~~

b) placing at least one temporary filter in said flowpath downstream from said cardiac valve, said filter being operative to restrict the passage of emboli while allowing blood to flow through said vessel

c) resecting or disrupting at least a portion of the cardiac valve; and

d) removing the temporary valve from the flow path.

49. (currently amended) A method for performing an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:

a) positioning a first valve as a ~~at least one~~ temporary valve in a flow path of blood without affixing the temporary valve to the blood vessel, said temporary valve being operative to effect greater antegrade flow than retrograde flow;

b) resecting or disrupting at least a portion of the cardiac valve; and

c) affixing a second valve as a ~~at least one~~ prosthetic valve at, upstream or downstream from said resected cardiac valve; and

d) removing the temporary valve from the flow path.

Applicant agrees to amend the abstract as follows:

The present invention discloses devices and methods for performing intravascular procedures with out:cardiac bypass. The devices include various embodiments of temporary filter devices, temporary valves, and prosthetic valves. The temporary filter devices have one or more cannulae which provide access for surgical tools for effecting repair of the cardiac valves. A cannula may have filters of various configurations encircling the distal region of the cannula, which prevent embolitic material from entering the coronary arteries and aorta.

The temporary valve devices may also have one or more cannulae which guide the insertion of the valve into the aorta. The valve devices expand in the aorta to occupy the entire flow path of the vessel. In one embodiment, the temporary valve is a disc of flexible, porous, material that acts to filter blood passing therethrough. A set of valve leaflets extend peripherally from the disc. [These leaflets can alternately collapse to prevent blood flow through the valve and extend to permit flow.

The prosthetic valves include valve fixation devices which secure the prosthetic valve to the wall of the vessel. In one embodiment, the prosthetic valves have at least one substantially rigid strut, at least two expandable fixation rings located about the circumference of the base of the apex of the valve, and one or more commissures and leaflets. The prosthetic valves are introduced into the vascular system a compressed state, advanced to the site of implantation, expanded and secured to the vessel wall.]

Applicant agrees to amend the specification as follows:

At the first line of the specification, amend to read:

This application is:

a continuation of United States Patent Application 09/700,167, filed 11/09/2000, now patent 6,896,690, which in turn is a 371 of PCT/US/00/02126, filed 01/27/2000, which claims benefit of U.S. provisional application 60/117,599, filed 01/27/1999, and claims benefit of U.S. provisional application 60/152,135, filed 08/25/1999, and claims benefit of U.S. provisional application 60/161,934, filed 10/28/1999.

***Allowable Subject Matter***

3. Claims 2, 48 and 49 are allowed. Reasons for allowance are as follows: after an extensive search of the art, claims and priority were found to predate all other existing applications of a similar nature, specifically, provisional application 60/117,599 disclosed the subject matter at hand prior to the closest available patent, Garrison 6,425,916. Specifically, the temporary nature of the temporary valve, which is implanted and subsequently removed immediately after the cardiac procedure is implemented - were found to define over the prior art in a novel and unobvious way.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Isabella David can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/  
Examiner, Art Unit 3774  
/Thomas J Sweet/  
Primary Examiner, Art Unit 3774